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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/506,651 | 11/16/2004 | Dimiter Stanchev Dimitrov | 015280-458000US | 3349 |

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| EXAMINER | |
|---|---|
| HUMPHREY, LOUISE WANG ZHIYING | |
| **ART UNIT** | **PAPER NUMBER** |
| 1648 | |

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/506,651 | DIMITROV ET AL. | |
| | Examiner | Art Unit | |
| | Louise Humphrey, Ph.D. | 1648 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-84 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-84 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

***Election/Restrictions***

Restriction is required under 35 U.S.C. §121 and §372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, 10, 50, and 55, drawn to the technical feature of a composition comprising a HIV envelope gp160 that is truncated at a position within 5 amino acids either side of amino acid 683 in SEQ ID NO:2.

Group II, claims 1, 3-5, 10, 50 and 55, drawn to the technical feature of a composition comprising a HIV envelope gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:2.

Group III, claims 1, 3, 4, 6, 10, 50 and 55, drawn to the technical feature of a composition comprising a HIV envelope gp160 that is SEQ ID NO:7.

Group IV, claims 1, 3, 4, 7, 9, 50, and 55, drawn to the technical feature of a composition comprising a HIV envelope gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:4.

Group V, claims 1, 3, 4, 8, 9, 50, and 55, drawn to the technical feature of a composition comprising a HIV envelope gp160 that is SEQ ID NO:8.

Group VI, claims 11-14, 20, 56, and 66, drawn to the technical feature of a method of manufacturing a HIV antigenic composition comprising a HIV envelope gp160 that is truncated at a position within 5 amino acids either side of amino acid 683 in SEQ ID NO:2.

Group VII, claims 11, 13-15, 20, 56, and 66, drawn to the technical feature of a method of manufacturing a HIV antigenic composition comprising a HIV envelope gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:2.

Group VIII, claims 11, 13, 14, 16, 20, 56, and 66, drawn to the technical feature of a method of manufacturing a HIV antigenic composition comprising a HIV envelope gp160 that is SEQ ID NO:7.

Group IX, claims 11, 13, 14, 17, 19, 20, 56, and 66, drawn to the technical feature of a method of manufacturing a HIV antigenic composition comprising a HIV envelope gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:4.

Group X, claims 11, 13, 14, 18, 19, 56, and 66, drawn to the technical feature of a method of manufacturing a HIV antigenic composition comprising a HIV envelope gp160 that is SEQ ID NO:8.

Group XI, claims 21-24, 30-32, 51, and 64, drawn to the technical feature of a vaccine comprising an aliquot amount of a HIV antigenic composition comprising a HIV gp160 that is truncated at a position within 5 amino acids either side of amino acid 683 in SEQ ID NO:2.

Group XII, claims 21, 23-25, 30-32, 51, and 64, drawn to the technical feature of a vaccine comprising an aliquot amount of a HIV antigenic composition comprising a HIV gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:2.

Group XIII, claims 21, 23, 24, 26, 30-32, 51, and 64, drawn to the technical feature of a vaccine comprising an aliquot amount of a HIV antigenic composition comprising a HIV gp160 that is SEQ ID NO:7.

Group XIV, claims 21, 23, 24, 27, 29, 31, 32, 51, and 64, drawn to the technical feature of a vaccine comprising an aliquot amount of a HIV antigenic composition comprising a HIV gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:4.

Group XV, claims 21, 23, 24, 28, 29, 31, 32, 51, and 64, drawn to the technical feature of a vaccine comprising an aliquot amount of a HIV antigenic composition comprising a HIV gp160 that is SEQ ID NO:8.

Group XVI, claims 33-36, 42-45, 52, 57, and 65, drawn to the technical feature of a method of protecting a human from HIV infection comprising administering to a human an amount of a HIV antigenic composition comprising a HIV gp160 that is truncated at a position within 5 amino acids either side of amino acid 683 in SEQ ID NO:2.

Group XVII, claims 33, 35-37, 42-45, 52, 57, and 65, drawn to the technical feature of a method of protecting a human from HIV infection comprising administering to a human an amount of a HIV antigenic composition comprising a HIV gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:2.

Group XVIII, claims 33, 35, 36, 38, 42-45, 52, 57, and 65, drawn to the technical feature of a method of protecting a human from HIV infection comprising administering to a human an amount of a HIV antigenic composition comprising a HIV gp160 that is SEQ ID NO:7.

Group XIX, claims 33, 35, 36, 39, 41, 43-45, 52, 57, and 65, drawn to the technical feature of a method of protecting a human from HIV infection comprising administering to a human an amount of a HIV antigenic composition comprising a HIV gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:4.

Group XX, claims 33, 35, 36, 40, 41, 43-45, 52, 57, and 65, drawn to the technical feature of a method of protecting a human from HIV infection comprising administering to a human an amount of a HIV antigenic composition comprising a HIV gp160 that is SEQ ID NO:8.

Group XXI, claims 46, 48, 53, 58, 60, 67, 68, 70 and 73, drawn to the technical feature of a nucleic acid comprising a coding sequence for a HIV gp160 that is SEQ ID NO:7.

Group XXII, claims 46, 48, 53, 58, 60, 67, 68, 72 and 73, drawn to the technical feature of a nucleic acid comprising a coding sequence for a HIV gp160 that is SEQ ID NO:8.

Group XXIII, claims 46, 48, 53, 58, 67-69, and 74, drawn to the technical feature of a nucleic acid comprising a coding sequence for a HIV gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:2.

Group XXIV, claims 46, 48, 53, 58, 67, 68, 71, and 74, drawn to the technical feature of a nucleic acid comprising a coding sequence for a HIV gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:4.

Group XXV, claims 47, 49, 54, 59, 61-63, 75, 77, 79, 83, and 84, drawn to the technical feature of a live recombinant vaccine comprising a nucleic acid comprising a coding sequence for a HIV gp160 that is SEQ ID NO:7.

Group XXVI, claims 47, 49, 54, 59, 61-63, 75, 77, 81, 83, and 84, drawn to the technical feature of a live recombinant vaccine comprising a nucleic acid comprising a coding sequence for a HIV gp160 that is SEQ ID NO:8.

Group XXVII, claims 47, 49, 54, 59, 62, 63, 75-78, 83, and 84, drawn to the technical feature of a live recombinant vaccine comprising a nucleic acid comprising a coding sequence for a HIV gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:2.

Group XXVIII, claim(s) 47, 49, 54, 59, 62, 63, 75-77, 80, 83, and 84, drawn to technical feature of a live recombinant vaccine comprising a nucleic acid comprising a coding sequence for a HIV gp160 that has at least 70% amino acid sequence identity to SEQ ID NO:4.

The inventions listed as Groups I-XXVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or

corresponding special technical features for the following reasons: the common technical feature among these Groups is a HIV antigenic composition comprising a HIV envelope gp160 having a gp120 subunit and a gp41 subunit wherein the carboxy-terminal end of gp120 is covalently linked through a peptide linker of at least 5 amino acids, to the amino-terminal end of gp41. Such a method is disclosed in Fouts *et al.* (2000) and Salzwedel *et al.* (2000). Since Applicant's inventive Groups do not contribute a special technical feature when viewed over the prior art, they do not have a single general inventive concept and thus lack unity of invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey Parkin, Ph.D.
Primary Examiner
05 October 2006

10/5/2006